



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-0001]

Annual Computational Science Symposium; Conference

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration, in cosponsorship with the Pharmaceutical Users Software Exchange (PhUSE) is announcing a public conference entitled “The FDA/PhUSE Annual Computational Science Symposium.” The purpose of the conference is to help the broader community align and share experiences to advance computational science. At the conference, which will bring together FDA, industry, and academia, FDA will update participants on current initiatives, and collaborative project groups will address specific challenges in accessing and reviewing data to support product development. These project groups will focus on solutions and practical ways to implement them.

DATES: The meeting will be held on March 13, 2016, from 3 p.m. to 7 p.m., and March 14 to 15, 2016, from 9 a.m. to 5:30 p.m.

ADDRESSES: The meeting will be held at the Silver Spring Civic Building at Veterans Plaza, One Veterans Pl., Silver Spring, MD 20910, 1-240-777-5300.

FOR FURTHER INFORMATION CONTACT: Chris Decker, PhUSE FDA Liaison Director, Pharmaceutical Users Software Exchange (PhUSE), Kent Innovation Centre, Broadstairs, Kent CT10 2QQ, United Kingdom; 1-609-514-5105 (US), css@phuse.eu.

SUPPLEMENTARY INFORMATION:

I. Background

Since 2008, the Office of Computational Science (formerly the Computational Science Center) of FDA's Center for Drug Evaluation and Research (CDER) has supported CDER's scientific community by offering innovative solutions that improve the scientific drug review process by integrating data, tools, services, and training. Since the first Computational Science Symposium four years ago, FDA has played an important part in the development and ongoing support of the conference and the associated PhUSE Computational Science Working Groups. The PhUSE Collaboration was formed to bring together experts from industry, FDA and other regulatory agencies, academia, and technology providers in specific areas to collaborate on computational science, describe best practices in challenging areas, and propose methods for addressing knowledge gaps. A description of the project groups and planned activities can be found at <http://www.phuse.eu/css.aspx>.

II. Registration and Accommodations

A. Registration

All registrants (with the exception of a limited number of speakers and/or organizers who will have a complimentary registration) will pay a fee for this meeting to help defray the costs of facilities, materials, and food. Seats are limited, and registration will be on a first-come, first-served basis.

To register, please complete the registration form online at <https://www.phuse.eu/PhUSE-CSS-2016-Registration.aspx>. (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document

publishes in the Federal Register). The costs of registration for the different categories of attendees are as follows:

Attendee category	Fee
Government/nonprofit/academia	\$300
Industry Organizing Committee & PhUSE Board of Directors (password required)	\$350
Poster presenter (includes the printing of the poster by PhUSE, password required)	\$375
Industry	\$750
Single-day	\$650
Registering after the conference begins	\$1250

Government and nonprofit attendees and exhibitors will need an invitation code to register at the discounted rate. An invitation code can be obtained by sending an email to: office@phuse.eu.

B. Accommodations

Attendees are responsible for their own hotel accommodations. Attendees making reservations at the DoubleTree by Hilton Silver Spring Hotel are eligible for a reduced rate of \$189 not including applicable taxes. Those making reservations online should use the following link to receive the reduced rate:

http://doubletree.hilton.com/en/dt/groups/personalized/D/DCASSDT-PHU-20160312/index.jhtml?WT.mc_id=POG.

If you need special accommodations because of disability, please contact Chris Decker (see FOR FURTHER INFORMATION CONTACT) at least 14 days in advance.

III. Transcripts

We expect that transcripts will be available approximately 30 days after the meeting. A transcript can be obtained either in hard copy or on CD-ROM, after submission of a Freedom of Information request. Send written requests to the Division of Freedom of Information (ELEM-

1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD

20857. Send faxed requests to 301-827-9267.

Dated: February 8, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-02877 Filed: 2/11/2016 8:45 am; Publication Date: 2/12/2016]